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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/911,423	08/14/97	GORMAN	D DX0612K1

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EXAMINER	
TUNG, M	
ART UNIT	**PAPER NUMBER**
1644	12

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 08/911,423	Applicant(s) Gorman, et al.
	Examiner Mary Tung	Group Art Unit 1644

☒ Responsive to communication(s) filed on *Mar 18, 1999*.

☒ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-43* is/are pending in the application.

Of the above, claim(s) *1-8, 13-16, 21, and 22* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *9-12, 17-20, and 23-43* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. Claims 1-22 were originally presented.
2. Claims 23-43 were added in the amendment filed 3/18/99 (Paper No. 11).
3. Claims 1-43 are pending.

In light of the amendment filed 3/18/99, Paper No. 11, only the following rejections remain:

Claim Rejections - 35 U.S.C. § 112

4. Claims 19 and 20 stand rejected under *35 U.S.C. § 112*, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claims 19 and 20 recite the phrase "at least about". This phrase renders the claim indefinite because the degree of deviation from the recited percent identity is unclear.

The following new grounds for rejection are necessitated by amendment:

Claim Rejections - 35 U.S.C. § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 9-12, 17-20 and 23-43 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is insufficient support in the specification or the claims as originally filed for the hybridization limitations recited in claims 9, 25, 26, 30, 32, 33, 37 and 43. Also, there is no support in the specification for the term, "mature polypaptide, as recited in claims 10, 30 and 40 and "mature coding" as recited in claim 24. Additionally, there is insufficient support in the specification or the claims as originally filed for the polynucleotide residue numbers recited in claim 32. **This is a new matter rejection**. The applicants may overcome this rejection (concerning claims 9, 25, 26, 30, 32, 33, 37 and 43) by reciting each of the components of the disclosed hybridization and wash conditions selected from the exemplary conditions listed on page 37 of the specification.

8. Claims 24, are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabled for polynucleotides encoding the amino acid sequence of SEQ ID NOS: 2 or 4, or for polynucleotides of SEQ ID NOS: 1 or 3, does not reasonably provide enablement for all "*variants*", "*conservative substitutions*" or "*allelic variants*" of such polynucleotides. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands* (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). The factors most relevant to this rejection are the scope of the claim, unpredictability in the art, the amount of experimentation required, and the amount of direction or guidance presented.

9. The specification disclosure is insufficient to enable one skilled in the art to practice the invention as broadly claimed without an undue amount of experimentation. Besides the nucleotides that encode SEQ ID NO: 2 and SEQ ID NO: 4, or the polynucleotides of SEQ ID NOS: 1 or 3, the specification fails to provide guidance as to how to determine the nucleic acid residues which will encode for functional fragments and variants of the gene product. While the specification defines polypeptide "*conservative substitutions*" as being "those nucleic acid sequences which encode identical or essentially identical amino acid sequences" (see page 7, lines 10-16) there is no disclosure of actual polynucleotides encoding "*variants*", "*conservative substitutions*" or "*allelic variants*" of SEQ ID NOS: 1 or 3 or "*variants*", "*conservative substitutions*" or "*allelic variants*" of polynucleotides encoding SEQ ID NOS: 2 or 4. Despite knowledge in the art for producing polynucleotide "*variants*", "*conservative substitutions*" or "*allelic variants*", the specification fails to provide guidance regarding what deletions from or alterations in the disclosed sequences result in polynucleotide "*variants*", "*conservative substitutions*" or "*allelic variants*" that encode a similar polypeptide. Furthermore, while recombinant techniques are available, it is not routine in the art to screen large numbers of polynucleotide fragments and variants where the expectation of retaining similar encoding function is unpredictable based on the instant disclosure. Detailed information regarding the structural and functional requirements of the polypeptide is lacking. Therefore, predicting which amino acid fragments and variants would maintain function is well outside the realm of routine experimentation; thus a skilled artisan would require guidance, such as information regarding the location, size, and sequence of deletions and alterations which preserve the encoding activity, in order to make and use polynucleotides, probes, vectors, host cells and recombinant methods in a manner reasonably commensurate with the scope of the claims.

10. In view of the quantity of experimentation necessary, the limited working examples, the unpredictability of the art, the lack of sufficient guidance in the specification, it would take undue trial and error to practice the claimed invention.

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 9-12, 17, 18 and 20-42 are rejected under *35 U.S.C. § 112*, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

13. Claims 9 and 37 recite the phrase "selectively hybridizes" which renders the claim indefinite. It is unclear which sequences would be encompassed by this limitation.

14. Claims 10, 30 and 40 recite the phrase "mature polypeptide", which renders the claim indefinite, since this term is not recognized in the art, nor is it defined in the specification.

15. Claim 10 lacks an antecedent basis as parts b), c) and d) recite polypeptide sequences, while the claim is drawn to a polynucleotide. Additionally, in part b), SEQ ID NOS: 1 or 3 are polynucleotide sequences, not polypeptide sequences.

16. Claims 11 and 12 lack an antecedent basis in the use of the phrase "said polynucleotide". It is suggested that the applicants replace the phrase with "the isolated or recombinant polynucleotide".

17. Claims 17, 18, 35, 36, 41 and 42 lack an antecedent basis for the phrase "said vector". It is suggested that the applicants replace the phrase with the phrase "the recombinant expression or replicating vector".

18. Claims 20-29 and 31-34 lack an antecedent basis in the use of the phrase "T[t]he polynucleotide". It is suggested that the applicants replace the phrase with "T[t]he isolated or recombinant polynucleotide".

19. Claim 31 is indefinite in the phrase "from SEQ ID NO: 4". SEQ ID NO: 4 is a polypeptide and thus it is unclear how a polypeptide sequence is part of a polynucleotide.

20. Claim 36 lack an antecedent basis for the term "said polypeptide". It is suggested that the applicants replace the phrase with "said antigenic polypeptide".

21. Claim 38 is indefinite in the term "mature coding portion", recited in part c), and "mature coding", recited in part d). The term "mature coding portion has no art-

recognized meaning, and there is no definition in the specification. Additionally, it appears that the word "portion" is missing from part d).

22. Claim 39 is indefinite in the use of the term "two-fold or less conservative amino acid substitution". It is unclear what substitutions are meant by this phrase. A substitution is either conservative or not, it is unclear how a substitution can be "two-fold or less".

23. Claims 17, 36 and 42 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: a host cell and obtaining or isolating the polypeptide from the culture fluid. It is suggested that the applicants render claim 17 dependent upon claim 18 and 36 dependent upon claim 35.

Allowable Subject Matter

24. Claims 9-12, 17-20 and 23-43 would be allowed, if the rejections under *35 U.S.C. 112, first and second paragraph* were overcome.

Conclusion

25. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

26. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

26. Papers related to this application may be submitted to Group 1640 by facsimile transmission. Papers should be faxed to Group 1640 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). THE CM1 FAX CENTER TELEPHONE NUMBER IS (703) 305-3014 or (703) 308-4242.

26. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Mary Tung whose telephone number is (703)308-9344. The Examiner can normally be reached Monday through Friday from 8:30 am to 5:30

pm. A message may be left on the Examiner's voice mail service. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1640 receptionist whose telephone number is (703) 308-0196.

June 4, 1999
Mary B. Tung, Ph.D.
Patent Examiner
Group 1640

DAVID SAUNDERS
PRIMARY EXAMINER
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